

U.S. Application No. 09/782,320

Bernhard van Lengerich

SECOND AMENDMENT AFTER FINAL UNDER 37 C.F.R. 1.116

And Record of Telephonic Interview

Attorney Docket No. BVL-102A

**REMARKS**

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, and 110 are pending, with claim 94 being the only withdrawn claim. By this amendment no claims have been amended, but the claims are presented in clean form for convenience of referral. No new matter has been introduced.

The election of species remains: (1) durum wheat as the plasticized matrix material, (2) a probiotic neutraceutical component as an encapsulant, (3) starch as the additional matrix material, and (4) liquid encapsulant as the encapsulant form. The claims readable on the elected species are Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110.

**Telephonic Interview**

Applicant thanks Examiner Lezah Roberts and Primary Examiner Patricia A. Duffy for the courtesy of a telephonic interview on April 5, 2011 with applicant's undersigned attorney Barry I. Hollander. The Examiners advised that they understood applicant's argument that the starch of Eden et al is totally destructed, highly crystalline, and not plasticized, and that applicant's starch is plasticized, amorphous and substantially non-destructed, and combining the Eden et al disclosure with the disclosure of Newton would not result in applicant's claimed invention. The Examiner's requested that applicant file a Second Amendment After Final Under 37 CFR 1.116 with the arguments as presented during the interview, so as to complete the record. The Examiners did not commit to allowance because they wanted to review plasticization and further consider the arguments. The arguments and substance of the interview are set forth below in further detail in connection with a response to the March 1, 2011 Advisory Action and the rejections set forth in the November 23, 2010 Final Rejection.

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Examiner Lezah Roberts confirmed that the Amendment After Final Rejection filed on January 21, 2011 would be entered upon the filing of an Appeal, even though in the Advisory Action paragraph 7 box b was not checked, because there had been no claim amendments in the January 21, 2011 Amendment After Final Rejection.

#### THE REJECTION UNDER 35 USC 112, FIRST PARAGRAPH

Claims 31, 59, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Applicant thanks the Examiner for indicating in the March 1, 2011 Advisory Action that applicant's arguments presented in the January 21, 2011 response were persuasive regarding the term "modified starch". However, regarding the derivatives of polyvinyl acetate it was indicated in the March 1, 2011 Advisory Action that the rejection was being maintained because applicant provides no other characteristics (other than the compounds are hydrophobic) or structure to indicate to one of skill in the art as to what structures are encompassed by the derivative, or the extent to which the polymer may be modified before it is no longer considered a derivative of polyvinyl acetate. According to the Advisory Action, one of ordinary skill in the art would not be able to immediately envision what compounds are encompassed by the recitation of polyvinyl acetate "derivatives." However, one of ordinary skill in the art would be able to immediately envision at least known polyvinyl acetate derivatives which are hydrophobic. The structure of polyvinyl acetate is known and the structure of numerous polyvinyl acetate derivatives are known to those skilled in the art. Indeed, Newton et al, cited by the Examiner, employs the term "derivatives" in connection with the broader phrase natural polymers and derivatives

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thereof, in the paragraph bridging columns 8 and 9, and col. 9 lines 18-21, and Wittwer et al employs the term “derivatives” in connection with the term starch (USP 4,738,724 at col. 7 line 67 to col. 8 line 24).

Furthermore, in the response filed on January 21, 2011, applicant has provided a plain, ordinary definition of the term “derivative” which may be employed by those skilled in the art. Applicant submits that for these reasons and for the reasons presented in the January 21, 2011 response, one ordinarily skilled in the art would readily understand how to make and use the claimed encapsulated products using the claimed polyvinyl acetate derivatives without undue experimentation.

This rejection was not discussed with the Examiners during the April 5, 2011 telephonic interview. However, applicant would consider amending “polyvinyl acetate and derivatives thereof” to “polyvinyl acetate” if requested to reduce the issues and place the application in condition for allowance.

Reconsideration and withdrawal of the rejection is respectfully requested.

#### THE REJECTIONS UNDER 35 USC 112, SECOND PARAGRAPH

Claims 31, 59, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed for reasons as presented above and in the Amendment After Final Rejection Under 37 CFR 1.116 filed on January 21, 2011, which reasons are incorporated herein in their entirety.

Applicant thanks the Examiner for indicating in the March 1, 2011 Advisory Action that applicant’s arguments presented in the January 21, 2011 response were persuasive regarding the term “modified starch”. However, regarding the derivatives of polyvinyl acetate it was indicated in the March 1, 2011 Advisory Action that the rejection was being

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maintained for the same reasons regarding the rejection under 35 U.S.C. 112, first paragraph.

The rejection of claims 31, 59, 108, and 109 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of use of the term “polyvinyl acetate derivative” is untenable for reasons as given above with respect to the rejection under the first paragraph of 35 U.S.C. 112. It is submitted that those skilled in the art would know the meaning of polyvinyl acetate derivatives, and applicant can claim as broadly as the art permits.

This rejection was not discussed with the Examiners during the April 5, 2011 telephonic interview. However, applicant would consider amending “polyvinyl acetate and derivatives thereof” to “polyvinyl acetate” if requested to reduce the issues and place the application in condition for allowance.

Reconsideration and withdrawal of the rejection is respectfully requested.

### **THE REJECTIONS UNDER 35 U.S.C. 103**

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397). This rejection is respectfully traversed.

In the March 1, 2011 Advisory Action, the Examiner admits that “Newton does not teach a plasticized matrix and asserts that the secondary reference, Eden, discloses a plasticized matrix and gives motivation as to why one of ordinary skill in the art would want to use a plasticized starch in the compositions of Newton.” However, as discussed with the Examiners during the April 5, 2011 telephonic interview, the Eden et al reference does not disclose production of a plasticized starch, and the Eden et al process does not inherently

produce a plasticized starch because, *inter alia*, as disclosed by the reference, Eden et al desires and obtains a cooked starch which is highly retrograded, or highly crystalline, and is not soluble in water, whereas a plasticized starch obtained by heating with low shear in an extruder to obtain a dough is amorphous or glassy. See Eden et al col. 1 lines 25-37. See the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 13 and 14, the paragraph bridging pages 25 and 26, and the first full paragraph on page 29. It was further pointed out that Eden et al does not disclose that the starch is plasticized and the Examiner has not provided any rationale as to why the starch of Eden et al is plasticized, or pointed to disclosure in the reference which supports the position taken in the Advisory Action that the starch is plasticized.

During the interview, the Examiners asked wouldn't the starch obtained by Eden et al be plasticized when the same temperatures are employed as those used by applicant? The Examiner's were advised that the highly retrograded starch of Eden et al is produced by a jet cooker using steam and is totally destructured, with the granular structure of the starch granules being totally destroyed, whereas applicant employs low shear extrusion. It was pointed out that it is believed that in the Eden et al process, the starch molecules in the starch granules are separated from each other and then crystallized, with the encapsulant entrapped between the crystallized starch molecules. The Examiners were advised that this is evidenced by Eden et al's disclosure that the starch molecules collapse on themselves forming a highly crystalline particulate-form matrix encapsulating the core material as disclosed at col. 1 lines 30-37.

Further, it was pointed out that as disclosed at col. 2 lines 34-47 and col. 4 lines 22-24 Eden et al employs a large amount of salt, which it is believed, is added to rapidly precipitate the starch molecules as small particles, such as only 5-7 microns in diameter, rather than to form a dough or plasticized mass. See col. 1 lines 50-54, col. 2 lines 52-56, and col. 4 lines 16-26. It was argued that Newton et al discloses it is critical to have particle

sizes of at least 2 mm (2000 microns) at col. 4 lines 63-65, which is much larger than the particle size obtained by Eden et al's process. The Eden et al process produces particles which are too small to employ effectively in the Newton et al product which requires a critically larger particle size for effectiveness, so there is no reason to use Eden's composition or method for the Newton et al composition. Also, the Examiners were advised that according to Eden et al, col. 4 lines 5-9, the starch is cooked even though a large amount of salt is present as a gelatinization inhibitor, further evidencing that total destructure occurs.

As argued during the interview, a dough or plasticized mass is not obtained and the starch is completely destructured in the process and product of Eden et al. However, in applicant's claimed product, the starch molecules are not substantially destructured. The encapsulation in applicant's product is not on a molecular basis, between crystallized starch molecules, but rather in a plasticized, glassy mass formed from a dough that has been dried, where the starch is not substantially destructured.

In the interview, the Examiners pointed out that the claims do not exclude destructure, but as argued by applicant's representative, the claims exclude the total or substantial destructure which is obtained by the Eden et al process. As set forth during the interview, a substantial portion of the starch in the products of the present invention does not have to be gelatinized at all, and at least a portion of the starch does not have to be gelatinized and can be in its native, granular form, which is distinctly different from the Eden product where no granular starch is present in the treated product. As emphasized during the interview, in the Eden et al product almost all starch molecules are collapsed molecules and are precipitated in a highly crystalline form, whereas in the plasticized mass of applicant, that portion of starch in the matrix that actually has been cooked, is in the amorphous or glassy, and essentially non-crystalline form.

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The Examiners questioned as to what was meant by plasticized, and as pointed out during the interview, as disclosed at page 9 of the present application the plasticized starch forms a dough, and some amylose and amylopectin may exude from the starch granules so that the granules stick together to form a dough, but the starch granules are not totally destructured so that the molecules collapse on each other and form a highly crystalline starch as in the Eden et al process and product.

Claims 34 and 61

During the interview, the Newton et al patent was also discussed and it was pointed out that claims 34 and 61 were patentable for the additional reason that they recite a density of 800 g/liter to 1500 g/liter (0.8 to 1.5 g/ml) whereas according to Newton et al at col. 5 lines 7-9, a higher density of above about 2 g/ml (2000 g/liter) is critical to Newton et al for achieving an increased residence time in the stomach. The Examiners asked whether applicant's recited upper limit of "about" 1.5 g/ml would overlap with the Newton et al critical amount of above about 2 g/ml. It was argued that the amounts would not overlap because Newton et al distinguishes a density of "about 1.0 to 1.5 g/ml" as being conventional at col. 2 lines 11-12 whereas it is taught that above about 2 g/ml is critical to the Newton et al product.

It is submitted for reasons as presented during the Examiner interview and as set forth above, even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

Newton et al alone or combination with Eden et al does not teach or suggest use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, and there is no reason to do so.

Reconsideration and withdrawal of the rejection is respectfully requested.

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Claims 42, 69, 70, 84, and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397) as applied above, in further view of Jane et al (U.S. Patent No. 5,397,834). This rejection is respectfully traversed for reasons as presented above and in the previous response.

In the March 1, 2011 Advisory Action, the Examiner maintains that Jane et al discloses the use of starch from durum wheat and Eden et al discloses the starch may be from wheat. It is asserted that the references do not exclude using starch that has not been isolated from its source and therefore it would have been obvious to use durum wheat because it is a source of starch. However, Jane et al discloses biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein, which according to Jane et al has very different texture, tensile strength, elongation, and water resistance compared to articles made from native starch and protein. See abstract and col. 1 lines 41-58. Even if Jane et al discloses that suitable starches include those derived from durum wheat, that is no reason to employ durum wheat in the products of Newton et al and Eden et al. Jane et al clearly desires aldehyde starch, not the raw material starch nor its source, such as durum wheat as a reactant reaction with the protein to make the thermoplastic. See col. 3 line 36 to col. 4 line 50. Durum wheat contains a high content of gluten which could interfere or compete with the desired reaction of Jane et al for making the aldehyde starch. In the Advisory Action, the Examiner asserts that heating the wheat would not appear to alter the properties to make it unsuitable for use in the compositions of the combination of Newton and Eden. However, the jet cooking employed by Eden et al could denature the protein of durum wheat, as well as completely destructure the starch as discussed above.

Jane et al does not cure the deficiencies in the disclosures of Newton et al and Eden et al discussed above and during the April 5, 2011 telephonic interview, and even if it were

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obvious to combine the teachings of Newton et al, Eden et al, and Jane et al, applicant's claimed invention would not be obtained nor rendered obvious.

The rejection is untenable and reconsideration and withdrawal thereof is respectfully requested.

## **CONCLUSION**

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

It is not believed that any additional fees are due. However, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,  
Bernhard H. van Lengerich



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